DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

July 16, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gary L. Verhoeven
250 Navajo Rd.
Hagerman, NM 88232

PURGED

Ref. # : DEN-99-13

Dear Mr. Verhoeven:

An investigation at your dairy operation located in Hagerman, New Mexico, was conducted by Consumer Safety Officer Barbara J. White. The inspection confirmed that you offered an animal for sale for slaughter as food, in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you caused animal drugs to become adulterated within the meaning of section 501(a)(5) of the Act.

On November 21, 1998, you offered a Holstein dairy cow, identified as USDA case number [redacted], for slaughter as human food to [redacted]. USDA analysis of tissue samples collected from this animal identified the presence of oxytetracycline residue of [redacted] ppm in the muscle, [redacted] ppm in the liver, and [redacted] ppm in the kidney. Tolerances of 2.0 ppm (muscle), 6 ppm (liver) and 12 ppm (kidney) have been established for residues of oxytetracycline in the edible tissues of beef cows in Title 21 Code of Federal Regulations Part 556.500 (21 CFR 556.500) at the time the analysis was conducted.

Our investigation revealed the use of [redacted] Oxytetracycline HCL Injection. The presence of this drug at the levels found in the edible tissue from this animal cause the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased and/or medicated animals bearing potentially harmful drug residues may enter the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

You are adulterating the drug [redacted] brand of Oxytetracycline HCL Injection that your firm uses on dairy cows within the meaning of section 501(a)(5) of the Act when you fail to use the drug in conformance with its approved labeling. Your use of the drug without following the labeling causes the drug to be unsafe for use. Animal drugs may be used for extra-label purposes under 21 CFR 530 if a veterinarian provides appropriate oversight to assure there will not be a residue. This does not appear to be the case in this incident. This drug prescription was obtained through initial contact with your drug distributor and not your veterinarian. You and others involved in this extra-label use can be held responsible for the tissue residue.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your operation into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,

for Richard A. Allaman

Gary C. Dean
District Director

cc: Ronald K. Jones, D.V.M.
Boulder District Manager
USDA/FSIS
665 S. Broadway, Suite B
Boulder, CO 80303

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